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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,013	08/06/2003	Steven W. Collier	PC23199A	1525
23913 7550 12/23/2008				
PFIZER INC				
Steve T. Zelson				
150 EAST 42ND STREET				
5TH FLOOR - STOP 49				
NEW YORK, NY 10017-5612				
EXAMINER				
SOROUSH, LAYLA				
ART UNIT		PAPER NUMBER		
1617				
MAIL DATE		DELIVERY MODE		
12/23/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/636,013

Applicant(s)

COLLIER ET AL.

Examiner

LAYLA SOROUSH

Art Unit

1617

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-11 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9-11 and 20-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The response filed September 17, 2008 presents remarks and arguments submitted to the office action mailed March 17, 2008 is acknowledged.

Applicant's presented no arguments over the Obvious Double Patenting rejection of U.S. Patent No. 6,861,413 and Application No. 10/355,575. The rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1, 9, 10, 16 and 17 over Curatolo et al. (EP 679 400) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1, 9, 10, 16, 17, 20, 21, 23 and 24 over Tenengauzer et al. (US 6,764,997) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 20, 21, 23 and 24 over Curatolo et al. (EP 679 400) in view of Tenengauzer et al. (US 6,764,997) or Li et al. (US 6,977,243) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 21 and 22 over Curatolo et al. (EP 679 400) in view of Tenengauzer et al. (US 6,764,997) or Li et al. (US 6,977,243) and further in view of Schwarz et al. (WO 2004/000865) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 23 and 24 over Curatolo et al. (EP 679 400) in view of Singer et al. (US 6,365,574) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 24 and 25 over Curatolo et al. (EP 679 400) in view of Singer et al. (US 6,365,574) and further in view of Schwarz et al. (WO 2004/000865) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 26 and 27 over Curatolo et al. (EP 679 400) in view of Karimian et al. (US 6,245,903) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 27 and 28 over Curatolo et al. (EP 679 400) in view of Karimian et al. (US 6,245,903) and further in view of Schwarz et al. (WO 2004/000865) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claim 11 over Curatolo et al. (EP 679 400) in view of Artman et al. (US 6,383,527) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

For Applicant's convenience the rejections of record are restated below:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 9-11, and 20-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,861,413 ('413). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention overlaps with that previously claimed. Thus, the instant claims are directed to a powder for oral suspension comprising (a) non-dihydrate azithromycin; (b) an azithromycin conversion stabilizing excipient, which is a non-ionic surfactant (electrolyte species); and (c) an azithromycin conversion enhancer (e.g. a flavorant or a volatile organic component).

The compositions may contain a non-viscosifying sweetener. The non-dihydrate azithromycin of the instant claims may be in the form of ethanol solvate (form F), isopropanol solvate (form M) or other forms. The claims of '413 are directed to a powder for oral suspension comprising (a) a n-propanol solvate of non-dihydrate azithromycin (form J); and (b) at least one pharmaceutically acceptable excipient.

The claims of '413 do not recite the non-ionic surfactant, conversion enhancer and/or a non-viscosifying sweetener of the instant claims. However, the portion of the specification in '413 that supports the recited "at least one pharmaceutically acceptable excipient", includes the non-ionic surfactant, conversion enhancer and/or a non-viscosifying sweetener that would anticipate the instant claims. The instant claims cannot be considered patentably distinct over Claims 1 and 2 of '413 when there is a specifically disclosed embodiment in the conflicting patent that supports Claim 1 of that patent and falls within the scope of Claims 1, 9-11, and 20-28 herein because it would have been obvious to one having ordinary skill in the art to modify the composition of Claim 1 of '413 by selecting a specifically disclosed embodiment that supports that claim, i.e., the specific pharmaceutically acceptable excipients disclosed in the conflicting patent. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment. With respect to the Claims 20, 23 and 26 of the instant invention, the claimed ethanol solvate and isopropanol solvate of azithromycin are obvious variants of the n-propanol solvate of azithromycin claimed in '413 because they are either positional isomers (iso-propanol vs. n-propanol) or homologs (ethanol vs. n-propanol). Nothing unobvious is seen in

substituting the known claimed isomer for the structurally similar isomer, since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. *In re Norris*, 84 USPQ 458 (1950).

Claims 1, 9-11, and 20-28 are directed to an invention not patentably distinct from claims 1 and 2 of commonly assigned U.S. Patent No. 6,861,413 ('413) for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 6,861,413 ('413), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claims 1, 9-10, 20, 23 and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 4 of copending Application No. 10/355,575 ('575). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention overlaps with that previously claimed. Thus, the instant claims are directed to a powder for oral suspension comprising (a) non-dihydrate azithromycin; and (b) an azithromycin conversion stabilizing excipient, which is a non-ionic surfactant (elected species). The powder of the instant claims further comprises (c) a conversion enhancer (e.g. a flavorant or a volatile organic component) as discussed above. The non-dihydrate azithromycin of the instant claims may be in the form of ethanol solvate (form F), isopropanol solvate (form M) or other forms. The claims of '575 are directed to a pharmaceutical formulation comprising (a) dry granulated particles of a non-dihydrate azithromycin selected from the group consisting of forms F, G and M; and (b) optionally, one or more pharmaceutically acceptable excipients. The claims of '575 do not recite the non-ionic surfactant or conversion enhancer of the instant claims. However, the portion of the specification in '575 that supports the recited "one or more pharmaceutically acceptable excipients", includes the non-ionic surfactant and conversion enhancers that would anticipate the instant claims. The instant claims cannot be considered patentably distinct over Claims 1, 3 and 4 of '575 when there is a specifically disclosed embodiment in the conflicting application that supports Claim 1 of that application and falls within the scope of Claims 1, 9-10, 20, 23 and 26 herein because it would have been obvious to one having ordinary skill in the art to modify the

composition of Claim 1 of '575 by selecting a specifically disclosed embodiment that supports that claim, i.e., the specific pharmaceutically acceptable excipients disclosed in the conflicting application. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that the Applicant intends to address the ODP issues of record once the claims of the instant application are otherwise in condition for allowance. See p. 5 of the reply.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400), of record.

Curatolo et al. teach a powder for oral suspension containing azithromycin, flavorants (e.g. vanilla, banana, etc.) and wetting agents such as sorbitan monolaurate and polysorbate 80. See p. 7, lines 2-37. The powder of Curatolo et al. may also contain artificial sweeteners. See p. 7, lines 20-21. The azithromycin of Curatolo et al. includes the pharmaceutically acceptable salts thereof, as well as *anhydrous* and hydrated forms. See p. 4, lines 39-40. The teaching of the "anhydrous" form of azithromycin anticipates the claimed limitation "non-dihydrated azithromycin". The flavorants of

Curatolo et al. anticipate the claimed limitation "an azithromycin form conversion enhancer"; the wetting agents of Curatolo et al. anticipate the claimed limitation "an azithromycin form conversion stabilizing excipient which is a surface tension reducing excipient". With respect to the claimed limitation "said surface tension reducing excipient is present in said powder for oral suspension in an amount sufficient to provide a surface tension of less than...", Curatolo et al. teach the concentration range of dispersing agents of 0.05 to 2% (see p. 7, line 5). Therefore, determination of optimal or workable concentration of the surfactant by routine experimentation within the reference generic disclosure is obvious absent showing of criticality of the claimed concentration. One having ordinary skill in the art would have been motivated to do this to obtain the desired dispersion of the active agent in the suspension as well as the desired stability of the preparation.

Claims 1, 9, 10, 20, 21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tenengauzer et al. (US 6,764,997), of record.

Tenengauzer et al. teach stabilized azithromycin dosage forms, including powders to make oral suspension, comprising flavorants such as vanilla, grape and banana ("an azithromycin form conversion enhancer" of the instant claims), wetting agents such as sorbitan monolaurate and polysorbate 80 ("an azithromycin form conversion stabilizing excipient" of the instant claims), and sweeteners. See col. 5, lines 9-24; col. 6, lines 32-60. Tenengauzer et al. teach azithromycin ethanolate monohydrate (form F) as the preferred azithromycin form. See col. 3, lines 1-6. The reference does not explicitly teach the claimed concentration of the surface tension reducing excipient

(i.e. wetting agent or surfactant). However, determination of optimal or workable concentration of the surfactant by routine experimentation is obvious absent showing of criticality of the claimed concentration. One having ordinary skill in the art would have been motivated to do this to obtain the desired dispersion of the active agent in the suspension as well as the desired stability of the preparation.

Claims 20, 21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of either Tenengauzer et al. (US 6,764,997) or Li et al. (US 6,977,243), all of record.

Curatolo et al. applied as above. The reference does not explicitly teach the claimed forms of azithromycin. However, Tenengauzer et al. teach using azithromycin ethanolate monohydrate (form F) in stabilized powders for oral suspensions as discussed above. Alternatively, Li et al. teach using the azithromycin forms of the instant claims in pharmaceutical compositions, including powders for oral suspensions. See col. 2-4; col. 26, lines 35-36. The crystal forms of azithromycin show improved stability as compared to form A. See col. 14, lines 40-50. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use azithromycin ethanolate monohydrate or other non-hydrate crystal forms of azithromycin instead of anhydrous azithromycin. One having ordinary skill in the art would have been motivated to do this to obtain improved stability of the compositions as suggested by either Tenengauzer et al. or Li et al.

The applied reference (Li et al.) has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of either Tenengauzer et al. (US 6,764,997) or Li et al. (US 6,977,243) and further in view of Schwarz et al. (WO 2004/000865), all of record.

Curatolo et al. in view of either Tenengauzer et al. or Li et al. applied as above. While generally teaching artificial sweeteners, Curatolo et al. does not explicitly teach the claimed sweeteners. However, Schwarz et al. teach using aspartame as an artificial sweetener in pharmaceutical compositions comprising azithromycin monohydrate as an

active ingredient. See p. 1, lines 11-19, 31-33. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use aspartame of Schwarz et al. as an artificial sweetener for its art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain the desired taste.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Singer et al. (US 6,365,574), both of record.

Curatolo et al. applied as above. The reference does not explicitly teach the claimed ethanol solvate form of azithromycin. However, Singer et al. teach using azithromycin ethanol solvate in pharmaceutical compositions because it is less hygroscopic than azithromycin monohydrate. See col. 1, lines 60-65; col. 3, line 26. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use azithromycin ethanol solvate. One having ordinary skill in the art would have been motivated to do this to obtain improved stability of the compositions as suggested by Singer et al.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Singer et al. (US 6,365,574) and further in view of Schwarz et al. (WO 2004/000865), all of record.

Curatolo et al. in view of Singer et al. applied as above. While generally teaching artificial sweeteners, Curatolo et al. does not explicitly teach the claimed sweeteners. However, Schwarz et al. teach using aspartame as an artificial sweetener in

pharmaceutical compositions comprising azithromycin monohydrate as an active ingredient. See p. 1, lines 11-19, 31-33. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use aspartame of Schwarz et al. as an artificial sweetener for its art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain the desired taste.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Karimian et al. (US 6,245,903), both of record.

Curatolo et al. applied as above. The reference does not explicitly teach the claimed isopropanol solvate form of azithromycin. However, Karimian et al. teach using azithromycin isopropanol solvate in pharmaceutical compositions because it is a non-hygroscopic form of azithromycin and, therefore, is more stable than anhydrous azithromycin. See col. 2, lines 35-41; col. 3, lines 22-60. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use azithromycin isopropanol solvate. One having ordinary skill in the art would have been motivated to do this to obtain improved stability of the compositions as suggested by Karimian et al.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Karimian et al. (US 6,245,903) and further in view of Schwarz et al. (WO 2004/000865), all of record.

Curatolo et al. in view of Karimian et al. applied as above. While generally teaching artificial sweeteners, Curatolo et al. does not explicitly teach the claimed sweeteners. However, Schwarz et al. teach using aspartame as an artificial sweetener in pharmaceutical compositions comprising azithromycin monohydrate as an active ingredient. See p. 1, lines 11-19, 31-33. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use aspartame of Schwarz et al. as an artificial sweetener for its art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain the desired taste.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Artman et al. (US 6,383,527), both of record.

Curatolo et al. applied as above. Curatolo et al. teach various flavorants as discussed previously. The reference does not teach the compounds claimed in the instant claim. However, it is well known in the art of pharmaceutical and food compositions to use isoamyl isovalerate of the instant claim as an FDA-accepted flavoring agent. See Artman et al. @ col. 8, lines 6-12. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use isoamyl isovalerate for its art-recognized purpose as a flavoring agent. One having ordinary skill in the art would have been motivated to do this to obtain the desired flavor/aroma of the composition.

Response to Arguments

Applicant's arguments submitted September 17, 2008 have been fully considered.

With respect to Applicants argument that the concentration range of dispersing agents of Curatolo is different from the surface tension reducing excipient recited in claim 1; and none of the combination of references suggests the unexpectedly improved stabilities of the claimed formulations," the Examiner respectfully states, Curatolo et al. teaches wetting agents such as polysorbate 80. Determination of optimal or workable concentration of the surfactant by routine experimentation within the reference generic disclosure is obvious absent clear showing of criticality of the claimed concentration. One having ordinary skill in the art would have been motivated to do this to obtain the desired dispersion of the active agent in the suspension as well as the desired stability of the preparation. With respect to the Tenengauzer et al. reference, while the concentration of the wetting agent (surfactant) is not explicitly taught, determination of optimal or workable concentration of the surfactant by routine experimentation is obvious absent showing of criticality of the claimed concentration. One having ordinary skill in the art would have been motivated to do this to obtain the desired dispersion of the active agent in the suspension as well as the desired stability of the preparation. The references both clearly state that the compositions of the prior art are stable. Hence, Applicants argument of unexpected stability is not persuasive.

Applicant argues "Tenengauzer does not disclose or describe a powder containing a surface tension reducing excipient that is a non-ionic surfactant wherein "said surface tension reducing excipient is present in said powder for oral suspension in

an amount sufficient to provide a surface tension of less than about 50 dynes/cm when an amount of said powder for oral suspension containing about 1, g of said non-dihydrate azithromycin is reconstituted with 10 ml of water" as recited in amended claim 1. Furthermore, applicants respectfully submit the data in the specification shows choosing surfactants with this property have unexpected results (i.e., inhibition of polymorph conversion). Accordingly, applicants respectfully submit that amended claim 1 is not obvious over Tenengauzer." In response, the Court has held that "the test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See *In re Rosselet*, 146 USPQ 183, 186 (CCPA 1965). "There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 USPQ2d 1481, 1489 (Fed. Cir. 1997). An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."). In this case, given that the prior arts teach the exact same active agents, non-ionic surfactant, and form conversion enhancer it would be obvious to

optimize the concentration of the surfactant by routine experimentation absent a clear showing of criticality of the claimed concentration. Additionally, the references clearly state that the compositions of the prior art are stable.

Applicant's argument over claims 11 and 21-28 rejections depends on the validity of the previous arguments which were not found persuasive.

The arguments are not persuasive and the rejection is made **FINAL**.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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